

**Remarks**

This Amendment is being filed concurrently with a Request for Continued Examination ("RCE"). The instant Amendment, which is filed in response to the final Office Action mailed May 15, 2009, and to the Advisory Action mailed August 27, 2009, replaces the Response Under 37 CFR § 1.116 filed August 17, 2009. Reconsideration and allowance of this application, as amended, are respectfully requested.

Applicants acknowledge with gratitude the personal interview conducted with the examiner and her supervisor at the U.S. Patent and Trademark Office on July 21, 2009. During the interview Applicants' representative first asked the examiner about the anticipation rejection based on Bormann. That is, in the Office Action, the examiner rejected claims as being anticipated by Bormann, but then acknowledged that Bormann does not meet each feature of the claimed invention, i.e., "Bormann does not appear to expressly disclose that the first porous element has higher hydrophilicity than the successive filter elements" (Office Action page 3, first full paragraph). Applicants pointed out that the anticipation rejection was, therefore, not warranted.

The examiner responded by saying that she was now essentially *revising* the ground of rejection. That is, the examiner said that "on a closer review of Bormann, Examples 1 and 4 show that the layers have a decreasing CWST and therefore decreasing hydrophilicity" (see Interview Summary page 2).

Turning to the present Amendment, claims 1, 10, 12, 20, and 21 have been amended to advance prosecution. Claims 11 and 15 have been canceled without prejudice or disclaimer. Claims 1, 3-10, 12-14, and 16-21 are now pending in the application. Claims 1 and 20 are independent. The rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments. Entry of each of the amendments is respectfully requested.

Claim 1 has been amended to incorporate features of the invention previously presented in now-canceled claims 11 and 15. Instant claim 1 defines an embodiment of the invention that includes, *inter alia*, "more than two porous elements being arranged in the filter device such that any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow, from said inlet to said outlet, of said blood product through said filter device." In addition, instant claim 1 recites that "an inlet porous element ha[s] a construction of material having a hydrophilicity as measured by a CST or a CWST value of the filtering material that is higher than 63 dyn/cm," and that "a difference between the hydrophilicity of the inlet porous element and a final outlet porous element, as measured by the CST or the CWST value of the filtering material, that is at least 10 dyn/cm." Claims 10 and 12 have been amended for consistency with

claim 1. Claim 20 has been amended in a similar manner. Claim 21 has been amended for consistency with claim 20.

By virtue of the claimed construction, a superior filter device results. See the results presented in Applicants' Examples 1-3 at specification pages 10-11. Filtration carried out with Applicants' claimed gradient filter device is clearly superior to conventional devices. See, e.g., Example 2, which uses a "filter consisting of 35 layers of coated PBT (50 g/m<sup>2</sup>) wettable with a 68 dyn/cm liquid and 5 layers of uncoated PBT (50 g/m<sup>2</sup>), CWST 53 dyn/cm." With the filter device of Example 2, the blood volume recovery is 92% and the number of residual white blood cells is 100,000/unit. However, as indicated at specification page 11, first paragraph, "[f]or a filter with a CWST of 53 dyn/cm *without the hydrophilicity gradient* the white blood cell contamination was found to be 1,100,000/unit" (emphasis added).

35 U.S.C. § 102(b)/§ 103(a) – Bormann / Bormann and Majurel

Claims 1, 3, 7-13, 16-18, 20, and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over WO 00/54873 of Bormann et al. (hereinafter "Bormann") as further evidenced by EP 0 542 655 to Majurel.

As indicated above, after rejecting all of the aforementioned claims as being anticipated by Bormann (Office

Action page 2), the examiner then acknowledges that Bormann does not meet each feature of the claimed invention, i.e., "Bormann does not appear to expressly disclose that the first porous element has higher hydrophilicity than the successive filter elements" (Office Action page 3, first full paragraph). To rectify the deficiency of Bormann, the examiner relies upon Majurel, asserting that "Majurel discloses a filtration device with different layers having increasing hydrophobicity from inlet to outlet, the increasing hydrophobicity of the layers improves the separation of blood components (Abstract)" (Office Action page 3).

The rejection of claims 1, 3, 7-13, 16-18, 20, and 21 under § 102(b) based on Bormann, or under § 103(a) based on Bormann and Majurel, is respectfully deemed to be obviated. For at least the following reasons, the disclosure of Bormann does not anticipate, and the combined disclosures of Bormann and Majurel would not have rendered obvious, Applicants' presently claimed invention.

By way of review, claim 1 defines an embodiment of the invention that includes, *inter alia*, "more than two porous elements being arranged in the filter device such that any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow, from said inlet to said outlet, of said blood product through said filter device." Consequently, the claimed filter device has a decreasing hydrophilicity profile (i.e., a negative gradient) in the direction of flow from inlet to

outlet. The instant specification provides evidence that the decreasing hydrophilicity profile is beneficial in that it leads to an improved leukocyte removal efficiency and to further advantages, such as reduced priming pressure and priming time of the filter (see, e.g., specification pages 8 and 9).

Bormann's filter is structurally and functionally different from Applicants' claimed filter device. The examiner concedes this deficiency at Office Action page 3. However, as pointed out above in the summary of the substance of the interview, the examiner asserts (i.e., not in the Office Action, but during the interview) that "on a closer review of Bormann, Examples 1 and 4 show that the layers have a decreasing CWST and therefore decreasing hydrophilicity" (Interview Summary page 2).

Applicants respectfully disagree with the examiner's assertion. As is evident from Bormann's Examples 1 and 4, the examiner's assertion is only partially accurate. In the description of Example 1, Bormann discloses a filter that has "6 first filter elements and 5 second filter elements" (Bormann page 21). The first filter element has "a CWST of 95 dynes/cm" and the second filter element has "a CWST of 65 dynes/cm." *But, Bormann also teaches that "[t]he first and second filter elements alternate, to provide a filter having 11 layers," and that "[t]he first filter element is utilized for layers 1, 3, 5, 7, 9, and 11, and the second filter element is utilized for layers 2, 4, 6, 8, and 10."*

Therefore, Bormann's alternating sequence of filters provides a configuration that is structurally different from Applicants' claimed filter device. That is, Bormann's layers 1, 2, and 3, for example, would have CWSTs of respectively, 95, 65, and 95. That, however, is not Applicants' claimed invention. Bormann's alternating sequence of filters is different from Applicants' claimed requirement that "any of said porous elements has a higher hydrophilicity than a successive porous element in a direction of flow" (claim 1).

Applicants also note that essentially the same points were made in Applicants' Amendment filed March 13, 2009. See the paragraph bridging Amendment pages 16 and 17, where Applicants explained that

In Bormann's Example 1, there are eleven alternating filter elements. The odd-numbered filter elements have a CWST of 95 dynes/cm, which is higher than the CWST of the even-numbered filter elements. The same situation applies to Bormann's Example 4. Therefore, in a filter configuration in which there are more than two filter elements, Bormann clearly discloses an *alternating* hydrophilicity profile from inlet to outlet. Clearly, Bormann does not teach a filter having a negative hydrophilicity profile, let alone Applicants' claimed filter device and all of the advantages associated therewith.

And now, to advance prosecution of this application, claim 1 has been amended to incorporate features of the invention previously presented in now-canceled claims 11 and 15. Instant claim 1 recites in pertinent part that "an inlet porous element ha[s] a construction of material having a hydrophilicity as

measured by a CST or a CWST value of the filtering material that is higher than 63 dyn/cm," and that "a difference between the hydrophilicity of the inlet porous element and a final outlet porous element, as measured by the CST or the CWST value of the filtering material, that is at least 10 dyn/cm."

Accordingly, since Bormann does not meet each feature of the claimed invention, Bormann does not anticipate the invention defined by Applicants' instant claim 1. Now-pending claims 3, 7-10, 12, 13, and 16-18 are allowable because they depend, either directly or indirectly, from claim 1, and for the subject matter recited therein.

Claims 20 and 21 are also allowable. Instant claim 20 defines an embodiment of the invention that includes, *inter alia*, "more than two porous elements disposed within said housing, each of said porous elements (i) being configured to remove leukocytes, (ii) *having at least two adjacent layers of a filtering material*, and (iii) having a different hydrophilicity relative to one another." In addition, claim 20 recites that "said more than two porous elements [are] arranged in the filter device such that, in said flow direction, *each of said porous elements has a higher hydrophilicity than a successive porous element*." The aforementioned configuration distinguishes over Bormann's filter elements that have the *alternating* hydrophilicity profile.

And, instant claim 20 also recites in pertinent part that "an inlet porous element located closest to said inlet ha[s] a construction of material having a hydrophilicity, as measured by a CWST value of the filtering material, that is at least 53 dyn/cm, and a difference between the hydrophilicity of the inlet porous element and a final outlet porous element located closest to said outlet, as measured by the CWST value of the filtering material, that is about 20 dyn/cm."

Bormann's alternating sequence of filters provides a configuration that is structurally different from Applicants' claimed filter device. Accordingly, since Bormann does not meet each feature of the claimed invention, Bormann does not anticipate the invention defined by Applicants' instant claim 20. Claim 21 is allowable because it depends from claim 20, and for the subject matter recited therein.

With regard to the obviousness portion of the rejection, Applicants respectfully submit that the disclosure of Majurel simply does not rectify any of the above-described deficiencies of Bormann. The examiner states that Majurel teaches that the increased hydrophobicity of the three-layer filter improves the separation of blood components. Applicants, however, can locate no such disclosure in Majurel. Clearly, the device which is disclosed by Majurel is not a leukocyte filter, but a device for the separation of erythrocyte agglutinates. Indeed, the composite membrane which is used to *obdurate* the capillary tube has a second



layer (intermediate layer) which is more hydrophobic than the first layer.

However, the purpose of Majurel's second layer is to prevent the flow during the incubation phase and has nothing to do with improving the separation of the blood components. (See the automated English-language translation, fourth paragraph from the bottom of page 1.)

Applicants respectfully submit that the third layer of Majurel's device is not a filter element at all, i.e., the "third, highly hydrophobic, external layer [is] pierced at its centre with an orifice with a diameter of approximately 0.1 mm" (Abstract). That is, the third layer has a relatively very large central hole and therefore is clearly an element which is specifically configured to allow the fluid to pass through the central hole, while not allowing the fluid to flow through the annular ring surrounding the hole. The annular ring is constructed of a highly hydrophobic material (i.e., "like polymeric of tetrafluoroethylene"). Clearly, the aforementioned configuration is not the principle of a filter element.

Accordingly, the combined disclosures of Bormann and Majurel would not have rendered obvious the invention defined by Applicants' instant claim 1. Now-pending claims 3, 7-10, 12, 13, 16-18, 20 and 21 are all allowable over the asserted combination of references for at least the same reasons as outlined above in response to the § 102(b) rejection.

35 U.S.C. § 103(a)

As urged in Applicants' Amendment filed March 13, 2009, since Bormann is the primary reference in each of the other rejections under § 103(a) -- claims 4 and 5 as being unpatentable over Bormann in view of U.S. Patent No. 4,925,572 to Pall; claim 6 as being unpatentable over Bormann in view of U.S. Patent No. 5,298,165 to Oka et al. ("Oka"); and claims 14 and 15 as being unpatentable over Bormann in view of U.S. Patent No. 5,190,657 to Heagle et al. ("Heagle") -- each of these rejections is also respectfully traversed. The combined disclosures of the cited references would not have rendered obvious Applicants' claimed invention because the disclosures of the additional references do not rectify any of the above-described deficiencies of Bormann.

Furthermore, there is simply no teaching in any of the references that would have led one to select the references and combine them in a way so as to arrive at the invention defined by any of Applicants' pending claims.

Therefore, the various combinations of references would not have rendered obvious the invention defined by any of Applicants' pending claims.

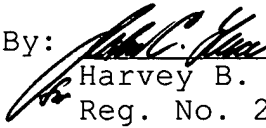
In view of the foregoing, this application is now in condition for allowance. If the examiner believes that another

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interview might expedite prosecution, the examiner is invited to  
contact the undersigned.

Respectfully submitted,

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